

c.) Remarks

Claim 1 has been amended in order to recite the present invention with the specificity required by statute. Additionally, claims 22 and 23 are amended for better idiomatic or grammatical usage. Accordingly, no new matter has been added.

Claims 1, 18 and 19 stand rejected under 35 USC § 112, first paragraph, and claims 1, 18, 19 and 22 stand rejected under 35 USC § 112, second paragraph. These are the sole outstanding issues, the Examiner having allowed claim 23 and reported that claims 1, 18, 19 and 22 are free of the prior art.

These rejections are addressed in turn.

In support of the enablement rejection, the Examiner states that while the artisan can make sequences capable of hybridizing to SEQ ID Nos 1-6 and 9-12 under the noted stringency conditions, and test the variants for specific properties, the specification fails to describe if these variants would retain any function of the parent molecule, or which sequences which are associated with IgA nephropathy.

In response, solely in order to reduce the issues, claim 1 now recites that the isolated DNA comprises SEQ ID NOS. 1-6 and 9-12, or SEQ ID NOS:39-42. Regarding SEQ ID NOS: 39-42, Applicants wish to point out that SEQ ID NOS:1-5 are cDNA sequences each contain a fragment whose expression level increases in IgA nephropathy

patients, see page 48, lines 8-13 (Example 3(1)) and Table 2 at page 59.^{1/} These fragments correspond to SEQ ID NOS:39, 40, 41 and 42, as shown in Table 1 at page 46.²

Accordingly, the DNA recited in the pending claims that hybridizes to SEQ ID NOS:1-5 and contain SEQ ID NOS:39-42 are considered to be of genes whose expression levels increase in IgA nephropathy patients.

As to the indefiniteness rejection, the recitation of “an isolated DNA which hybridizes with the isolated DNA immobilized” has been clarified and the term “homology” has been deleted. Additionally, the preamble in claim 22 now recites detecting “mRNA which comprises a nucleotide sequence selected from the group of nucleotide sequences consisting of SEQ ID NOS:1-6 and 9-12.”

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1, 18, 19, 22 and 23 remain presented for continued prosecution.

^{1/} Specifically, the sequences of SEQ ID NOS:1-5 correspond to cDNA sequences of genes of INP303A, INP377A, INP379A, INP401A and INP401A, respectively.

^{2/} SEQ ID NO:39: complementary strand of 2797-3101 of SEQ ID NO:1; SEQ ID NO:40: complementary strand of 759-1014 of SEQ ID NO:2; SEQ ID NO:41: complementary strand of 2706-2949 of SEQ ID NO:3; and SEQ ID NO:42: complementary strand of 960-1217 of SEQ ID NO:4 and complementary strand of 1313-1570 of SEQ ID NO:5.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lawrence S. Perry", written over a horizontal line.

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Revised Notice*

AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT

The United States Patent and Trademark Office (USPTO) is permitting applicants to submit amendments in a revised format as set forth below. Further details of this practice are described in *AMENDMENTS IN A REVISED FORMAT NOW PERMITTED*, signed January 31, 2003, expected to be published in *Official Gazette* on February 25, 2003 (Notice posted on the Office's web site at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>). The revised amendment format is essentially the same as the amendment format that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. The Office plans to adopt such a revision to 37 CFR 1.121 by July of 2003, at which point compliance with revised 37 CFR 1.121 will be mandatory.

Effective immediately, **all** applicants may submit amendments in reply to Office actions using the following format. Participants in the Office's electronic file wrapper prototype¹ receiving earlier notices of the revised practice may also employ the procedures set out below.

REVISED FORMAT OF AMENDMENTS

Begin on separate sheets:

Each section of an Amendment (e.g., Claim Amendments, Specification Amendments, Drawing Amendments, and Remarks) should begin on a separate sheet. *For example*, in an amendment containing a.) introductory comments, b.) amendments to the claims, c.) amendments to the specification, and d.) remarks, each of these sections must begin on a separate sheet. This will facilitate the process of separately indexing and scanning of each part of an amendment document for placement in an electronic file wrapper.

Two versions of amended part(s) no longer required:

The current requirement in 37 CFR 1.121(b) and (c) to provide two versions (a clean version and a marked up version) of each replacement paragraph, section or claim will be waived where an amendment is submitted in revised format below. The requirements for substitute specifications under 37 CFR 1.125 will be retained.

A) Amendments to the claims:

Each amendment document that includes a change to an existing claim, or submission of a new claim, **must include a complete listing** of all claims in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.

- (1) The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given. Status is indicated in a parenthetical expression following the claim number by one of the following: (original), (currently amended), (previously amended), (canceled), (withdrawn), (new), (previously added), (reinstated – formerly claim #), (previously reinstated), (re-presented – formerly dependent claim #), or (previously re-presented). The text of all pending claims under examination must be submitted each time any claim is amended. Canceled and withdrawn claims should be indicated by only the claim number and status.
- (2) All claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim should be shown by strikethrough (for deleted matter) or underlining (for added matter). An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended" will include markings.
- (3) The text of pending claims not being amended must be presented in clean version, i.e., without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version.

¹ The Office's Electronic File Wrapper prototype program is described in *USPTO ANNOUNCES PROTOTYPE OF IMAGE PROCESSING*, 1265 Off. Gaz. Pat. Office 87 (Dec. 17, 2002) ("Prototype Announcement"), and applies only to Art Units 1634, 2827 and 2834.

- (4) A claim may be canceled by merely providing an instruction to cancel. Listing a claim as canceled will constitute an instruction to cancel. Any claims added by amendment must be indicated as (new) and shall not be underlined.
- (5) All of the claims in each amendment paper must be presented in ascending numerical order. Consecutive canceled or withdrawn claims may be aggregated into one statement (e.g., Claims 1 – 5 (canceled)).

Example of listing of claims (use of the word “claim” before the claim number is optional):

Claims 1-5 (canceled)

Claim 6 (withdrawn)

Claim 7 (previously amended): A bucket with a handle.

Claim 8 (currently amended): A bucket with a ~~green~~ blue handle.

Claim 9 (withdrawn)

Claim 10 (original): The bucket of claim 8 with a wooden handle.

Claim 11 (canceled)

Claim 12 (re-presented – formerly dependent claim 11) A black bucket with a wooden handle.

Claim 13 (previously added): A bucket having a circumferential upper lip.

Claim 14 (new): A bucket with plastic sides and bottom.

B) Amendments to the specification:

Amendments to the specification must be made by presenting a replacement paragraph or section marked up to show changes made relative to the immediate prior version. An accompanying clean version is not required and should not be presented. If a substitute specification is being submitted to incorporate extensive amendments, both a clean version (which will be entered) and a marked up version must be submitted as per current 37 CFR 1.125.

C) Amendments to drawing figures:

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with § 1.84. An explanation of the changes made must be presented in the remarks section of the amendment. Any replacement drawing sheet must include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. The figure or figure number of the amended drawing should not be labeled as “amended.” If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Any questions regarding the submission of amendments pursuant to the revised practice set forth in this flyer should be directed to the following legal advisors in the Office of Patent Legal Administration (OPLA): Elizabeth Dougherty (Elizabeth.Dougherty@uspto.gov), Gena Jones (Eugenia.Jones@uspto.gov) or Joe Narcavage (Joseph.Narcavage@uspto.gov). For information on the waiver or legal aspects of the prototype, please contact Jay Lucas (Jay.Lucas@uspto.gov), Senior Legal Advisor (PCTLA) or Rob Clarke (Robert.Clarke@uspto.gov), Senior Legal Advisor (OPLA). Alternatively, further information may be obtained by calling OPLA at (703) 305-1616.

* Revised Notice: See Sec. B) for changes relating to substitute specifications, and Sec. C) for changes on replacement drawing practice.